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Original Article

Long-Term (10–15 years) Follow-up after Burch Colposuspension for Urinary Stress Incontinence

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EXHIBIT # 6
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9/26/15 ncv

Abstract: The study group comprised 127 patients who underwent a Burch colposuspension for urinary incontinence. All had undergone urodynamic investigation both pre- and postoperatively. All patients had a mean follow-up of 12.4 years (range 10–15); 109 patients had an additional urodynamic investigation at least 10 years after the operation. Following surgery there was an improvement in symptoms of frequency ($P<0.001$), urgency ($P<0.01$) and urge incontinence ($P<0.001$). The cure rate was 93.7%. The only significant changes found on urodynamics were the measurements of the pressure transmission ratio, which were higher postoperatively ($P<0.001$) and remained so after 10 years. The most frequent postoperative complications were de novo detrusor instability (16.6%) and anatomical defects (18.7%). All failed cases were found during the first postoperative year. De novo detrusor instability appeared in 12/17 patients during the first year of follow-up. Postoperative anatomical defects were found only in 4/24 patients after 5 years. Ten years postoperatively most of the anatomical defects had been detected (20/24), stressing the need for long-term follow-up.

Keywords: Burch colposuspension; Complications; Cure rate; Long-term follow-up

Introduction

There are numerous papers concerning different techniques for the surgical treatment of female stress incontinence. Among the suprapubic procedures the Burch colposuspension is one of the most popular, as it seems to give the best results. Nevertheless, the continence rate following Burch colposuspension varies between 67% and over 95% [1–4]. This wide range depends on the criterion for defining cure, the lack of objective evaluation, patient selection and the length of follow-up.

The purpose of this study was to evaluate the long-term clinical, urodynamic data and associated complications following Burch colposuspension for urinary stress incontinence.

Materials and Methods

During 1982–1987 156 consecutive patients underwent a Burch colposuspension procedure for urinary stress incontinence. Postoperative clinical assessment was performed at 3, 6 and 12 months, and once a year thereafter. Urodynamic investigation was performed 6–12 months postoperatively and during 1996.

Of the 156 patients, 29 were omitted for not completing the 10-year follow-up (8 patients died from unrelated causes and 21 patients could not be located). The study group comprised 127 patients, of whom 109 agreed to urodynamic investigation during 1996. The mean duration of follow-up was 12.4 years (range 10–15 years).

Preoperatively, all subjects had a full history taken and underwent gynecologic, urologic and neurologic system examination. Patients were examined with a full bladder for the visual appearance of urinary incontinence. The urodynamic investigation included twin-channel substracted cystometry, uroflowmetry and urethral pressure profile measurements. Cystometry and uroflowmetry were performed using the Urinary

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Investigation System 5000 (Lectromed, Jersey, UK). Measurements were made with the patient in the supine and standing positions using saline solution as the filling substance, at room temperature and at an infusion rate of 100 ml/min. Urethral profile pressures were performed using the 7F Gaeltec dual microtransducer catheter (Gaeltec, Glasgow, Scotland). The bladder was filled with 300 ml saline in the supine position. These tests at rest and at stress in the supine position have been described elsewhere [5]. From the stress profiles we calculated pressure transmission ratios at four equidistant points along the functional urethral length. The operative procedure for correcting urinary stress incontinence was a modified Burch colposuspension [6], using two to three pairs of no. 1 absorbable sutures. The most caudal pair was inserted at the level of the bladder neck, and the other two pairs were inserted more cephalad alongside the bladder base. Of the entire group, 48 patients had a Burch colposuspension only and 79 had a concomitant abdominal hysterectomy for gynecologic indications. Cure was defined as subjective and objective dryness. The methods, definitions and units conform to the standards proposed by the International Continence Society [7]. The statistical method used was McNemar's paired χ^2 test.

Table 1. Patients' characteristics (n = 127)

Age	49.2±5.1	(29–79)
Parity	3.1±1.8	(1–10)
Duration of symptoms (years)	4.7±2.7	(1–17)
Premenopausal	56	(44.0%)
Postmenopausal	71	(56.0%)
*Previous incontinence surgery	23	(18.1%)
Genuine stress incontinence	102	(80.3%)
Mixed stress incontinence	25	(19.7%)

* Vag. Hysterectomy and Ant. Repair = 14. Ant. Repair/Kelly's suture = 5. MM-3 Stamey = 1.

Table 2. Pre- and postoperative clinical data (n = 127)

	Pre-Op		Postop. (1 year)		1996		
	n	%	n	%	$P<$	n	%
Frequency							
Diurnal	66	51.9	31	24.4	0.001	33	25.9
Nocturnal	54	42.5	22	17.3	0.001	25	19.6
Urgency	71	55.9	32	25.2	0.01	37	29.1
Urge incontinence	42	33.0	12	9.4	0.001	13	10.2
Stress incontinence	127	100	*8	6.3	0.001	2	

* Six patients were reoperated.

Results

One hundred and twenty-seven patients completed at least the 10-year follow-up. Table 1 describes the patient characteristics. The mean age was 49.2 years; 23 patients (18.1%) had had previous anti-incontinence surgery; 58 (45.6%) had undergone Burch colposuspension only; the other 69 (54.4%) had had adjuvant surgery, mainly abdominal hysterectomy. Following surgery, as detected from a restrospective chart review, there was an immediate significant relief in the symptoms of frequency (P<0.001), urgency (P<0.01), urge incontinence (P<0.001) and stress incontinence (P<0.001) which remain throughout the years of follow-up (Table 2). The failure rate was 6.3%. All failed cases were found within the first postoperative year and 6 of those patients were reoperated. There were no changes in the cystometric and uroflowmetry parameters in the immediate and long-term measurements (Table 3). On urethral pressure profile measurements (Table 4) the pressure transmission ratio was found to be significantly higher after 1 year (P<0.001) and still significantly higher at the measurements during 1996 (P<0.005).

The most frequent postoperative complications were detrusor instability in 29 patients (22.2%) and anatomical defects in 24 patients (18.7%). Other complications, as listed in Table 5 appeared much less frequently. Concerning the appearance of detrusor instability, we divided the patient group into those with preoperative stable bladder (102 patients) and those with preoperative mixed incontinence (25 patients). Postoperatively the preoperative stable bladder group developed de novo detrusor instability in 17 cases (16.6%), whereas in the mixed incontinence group 13 out of 25 patients (52%) had stable bladders on cystometry postoperatively. Table 6 summarizes the time of diagnosed postoperative complications. Recurrent urinary stress incontinence was found in 8 patients, all of them in the first 12 months of follow-up. Six patients were successfully

Table 3. Urodynamic data (n = 109)

	Preop	Postop 1 yr	Postop 1996
Capacity (ml)	486.2±58.7	474.3±49.8	459.5±52.3
Residual volume (ml)	19.4±24.6	22.9±34.2	24.6±32.8
Pressure rise on filling (CmH_2O)	12.9±7.1	13.6±8.3	13.9±7.9
Pressure rise on standing (cmH_2O)	9.3±7.8	10.8±7.4	11.8±7.5
Maximal voiding pressure (CmH_2O)	36.8±10.4	35.2±11.6	33.8±10.7
Peak flow rate (ml/s)	27.6±7.4	25.9±7.3	24.3±7.6

P = NS for each value.

Table 4. Urethral pressure profile (n = 109)

	Preop	Postop (1 yr)	P<	Postop (1996)	P<
At rest					
Absolute length (mm)	46.8±7.0	47.1±9.3	NS	46.2±9.6	
Functional length (mm)	38.2±4.9	39.9±7.4	NS	37.1±8.3	
Maximal urethral pressure (CmH_2O)	53.2±16.1	54.7±14.9	NS	46.8±15.4	NS
Maximal urethral closure pressure (CmH_2O)	46.9±15.3	45.8±13.9	NS	43.1±14.7	
Pressure transmission ratio (%)					
Q_1	84.6±11.2	106.7±12.3	0.001	100.3±11.6	0.005
Q_2	86.3±9.4	107.9±14.0	0.001	102.5±15.4	0.005
Q_3	74.7±16.3	97.3±16.8	0.005	82.4±17.3	NS
Q_4	65.1±15.8	81.4±19.3	0.05	70.1±16.7	NS

Table 5. Postoperative complications (n = 127)

Detrusor instability	29 (22.2%)
Rectoenterocele	18 (14.1%)
Vault prolapse	4 (3.1%)
Uterine prolapse	2 (1.5%)
Vesicovaginal fistula	1 (0.8%)
Dyspareunia	5 (3.9%)
Recurrent USI	8 (6.2%)
Late voiding difficulties (residual volume more than 100 ml)	5 (3.9%)
Recurrent UTI (more than 3 episodes/year)	6 (4.7%)

reoperated. De novo detrusor instability was found in 17 patients, the majority of them (12 patients) being diagnosed during the first postoperative cystometry. The same applies to the disappearance of detrusor instability in the preoperative mixed incontinence group, where 10/25 patients were found to have a stable bladder during their first postoperative cystometry. Postoperative anatomical defects were found in 24 patients. In the first 2 postoperative years only 4 patients were found with anatomical defects. After 5 years less than half (11/24) were found to have anatomical defects. Ten years postoperatively most of the anatomical defects (20/24) had been found. We tried to detect risk factors for failed surgery, and found that pre- and postoperative detrusor instability, previous incontinence surgery, advanced age and menopausal status appear more frequently in the failed group. The differences did not reach statistical significance, probably because of the small number of failed cases.

Discussion

The importance of long-term follow-up after Burch colposuspension has already been advocated [6]. Nevertheless, although this is probably the most popular surgical procedure for urinary incontinence ony a few studies have reported on its long-term effectiveness on the basis of subjective and objective pre- and postoperative assessment by urodynamic measurements. Some studies suggested that the cure rate declines over the years, from 92% after 1 year to 69% after 10 years [4]. A less pronounced decline was found by others [8], form 97.3% after 1 year to 90.3% after 10 years. Our results disagree with these findings, as after the first postoperative year found no further failures. These findings are in accord with other publications [9], which found a constant continent rate from the second to the 10th postoperative years.

Our long-term urethral pressure profile measurements reveal that there are no changes in urethral length and urethral closure pressure between the pre- and postoperative measurements. These results confirm the findings of the short postoperative follow-up [10], in contrast to others [3], who found a significant increase in urethral functional length and urethral closure pressures. The only significant changes found on urethral pressure profile measurements in this study were higher transmission ratios found postoperatively in both the short and the long-term measurements. Only a single paper [3] was found that measured pressure transmission ratios in the long-term follow-up, supporting our findings.

Table 6. Time of diagnosed postoperative complications

	1 yr	2 yrs	5 yrs	10 yrs	15 yrs
Recurrent stress incontinence	*8	2	2	2	2
De novo DI (preoperative stable bladder 102 patients)	12	14	16	16	17
DI (preoperative mixed incontinence 25 patients)	10	10	10	11	12
Rectoenterocele (18) Vault prolapse (4) Uterine prolapse (2) — 24 patients	2	4	11	20	24

* Six patients were reoperated.

The major postoperative complications found in our series were detrusor instability (22.2%) and anatomical defects (18.7%) Detrusor instability is a well recognized complication following Burch colposuspension. In dealing with this complication one should separate those patients with preoperative mixed incontinence from those with a preoperative stable bladder who develop de novo detrusor instability postoperatively. This latter group has been reviewed in the literature [11]. Six studies were reviewed, with a total of 396 patients, 17% of whom devleoped de novo detrusor instability. The prevalence varied from 5% to 27%. These figures were confirmed in a more recent work [4], as in the present series (16.6%). Our results indicate that 14/17 patients developed (de novo) detrusor instability in the short postoperative period, and only few others developed de novo instability over the years. On the other hand, patients with preoperative mixed incontinence in the present series were cured from detrusor instability following surgery in 50% of cases, as previously reported by us [12] and reviewed by others [11]. In a review of five papers the authors found a 55% cure rate for detrusor instability following Burch colposuspension (range 66%–15%). To date no satisfactory explanation as to why patients with preoperative detrusor instability are cured of their detrusor instability following Burch colposuspension can be provided, maybe because in the majority of cases detrusor instability is still idiopathic in origin.

Anatomical defects following Burch colposuspension were found in 18.7% of our patients. We included rectoenterocele (14.1%), vault prolapse (3.1%) and uterine prolapse (1.5%), all of which were severe enough to require surgical repair. These figures confirm other publications finding anatomical defects ranging from 7.6% to 26.7% [1,2,4]. The most acceptable explanation for this complication is the rotation of the vaginal axis anteriorly, allowing intra-abdominal pressure to be transmitted through the posterior cul de sac. Another possibility is that candidates for colposuspension have predisposing relaxation of the pelvic floor, with a greater tendency to develop anatomical defects. Our opinion is that both these theories combine, as patients with marked pelvic relaxation are candidates for Burch colposuspension, whereas those without marked pelvic relaxation tend to undergo minor procedures, such as needle suspension or vaginal slings. Postoperative anatomical defects are not recognized as a major complication following these minor procedures. The different rates of anatomical defects following Burch colposuspension may be explained by the various techniques with which this operation is performed, patient selection, the inclusion or not of rectocele as an anatomical defect following surgery, and the duration of follow-up. Our results indicate that long-term follow-up has been proved essential in tracing cases of anatomical defects, as more than 50% of our cases were detected after 5 years of follow-up, stressing the importance of long-term follow-up after Burch colposuspension.

Risk factors for failed surgery have been previously identified in the literature [2–4]: they include previous incontinence surgery, detrusor instability and advanced age. Our results, although not reaching statistical difference, tend to confirm these factors as imposing an increased risk of failure following Burch colposuspension.

In summary, our long-term cure rate with Burch colposuspension was found to be comparable with that reported by others. This was expressed objectively by the high pressure transmission ratios fond on urethral pressure profile measurements 10–15 years after surgery. All our failures occurred within the first postoperative year. The most significant complications are de novo detrusor instability (16.6%) and anatomical defects (18.9%), half of which appeared only 5 years postoperatively, stressing the need for long-term follow-up.

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EDITORIAL COMMENT: As the results of this study indicate, there remains little doubt that in the hands of expert surgeons the Burch colposuspension is a durable and effective operation for uncomplicated stress urinary incontinence. Even if one considers the most pessimistic possible results of this study, i.e. that all of the patients lost to follow-up and who did not have follow-up urodynamic

study had failed, the 10-year cure improvement rate is still 70%.

There are two aspects of this study that merit discussion: the methods of outcome analysis, and defining the role of Burch colposuspension in routine practice.

The authors utilized excellent objective outcome tools (urodynamic studies and examination with a full bladder) before and after treatment. Using these tools they demonstrated an objective cure rate of 92%, although de novo detrusor instability occurred in 17% of the patients, detrusor instability persisted in 48% of patients with mixed incontinence, and genital prolapse occurred in 19% of the patients. Unfortunately, the authors did not specify whether the detrusor instability was symptomatic or not. For those with urge incontinence due to detrusor instability 'cure' is not an apt term, because most patients find urge incontinence to be a much bigger problem then stress incontinence.

The authors did not assess the patients' subjective outcome analysis in any structured way. The relationship between objective evaluation and subjective symptoms is an imperfect one. Some patients say they are cured yet objective testing shows they are still wet; others say they are still wet in their daily lives, yet objective testing shows they are cured. Any assessment, then, must take these factors into account.

Recently Groutz et al. [1] presented a new outcome assessment score based on a 24-hour voiding diary, pad test and simple patient questionnaire. Using this tool in patients previously reported to have a cure improve rate of 82%, the cure rate was only 45%. The cure improve rate remained the same, but this is because many patients formally thought to be cured were, in fact, improved.

Should a patient who is cured of stress incontinence and has refractory urge incontinence be considered cured? I think not, but I leave it to the individual reader to come to his or her own conclusion.

What should the role of Burch colposuspension be in routine clinical practice? In terms of durability I believe that, along with pubovaginal sling, Burch should be considered the gold standard for the treatment of stress urinary incontinence [2]. Admittedly I am biased towards the pubovaginal sling because of my own experience with it [3]. No procedure, even the pubovaginal sling, has as many papers that reflect long-term data, (i.e. 10 years or more). For this reason alone it should be considered a gold standard.

There are, however, some pitfalls when considering the Burch a gold standard. First, as seen in this paper, most of the patients who underwent surgery were younger (i.e. mean age of 49 years) and had undergone fewer previous anti-incontinence surgeries (18%). In addition, the series of patients did not include very many (if any) complicated patients, compared to series of pubovaginal sling patients [2,3]. For this reason, i.e. that former studies are not only of shorter duration but include many more patients with multiple operations and other complexities which reduce the likelihood of long-term success, it is difficult to compare pubovaginal slings with Burch. Nevertheless, in our judgment the Burch should be restricted to women with simple stress incontinence associated with urethral hypermobility. For those with intrinsic sphincter deficiency and or complicated problems, the pubovaginal sling is more appropriate.

For clinicians experienced in doing Burch colposuspension whose results are good, I think it most prudent for them to continue to do so. For those experienced in doing fascial pubovaginal slings, they should continue to do so. For those new to the field, I recommend that they learn one or another of these techniques and leave it to those in the business of clinical research to define the proper role of the newer techniques that are currently gaining favor. However, for patients with complex sphincteric incontinence I believe autologous fascial pubovaginal sling is the operation of choice.

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Regarding long term studies with autologous PVS & Burch:

1. This is comparing apples to oranges since the PVS does NOT have any foreign bodies (except maybe Prolene suture which Ethicon says is inert and safe).

2. The autologous PVS is NOT a permanent implantable medical device like TVT

   - Rosenzweig 9-22-15 (Rough txt pg 226/375 or 178, ln 23)

     Q: The autologous pubovaginal sling is not a medical device, right?

     … A: Autologous, that is not a medical device.

THEREFORE:

1. Autologous PVS and TVT are apples and oranges!

a. The TVT is a permanent implantable medical device, therefore, studies must be for the duration of the patient (ie. lifelong) to assess the lifelong risk to the patient.

(Exp Rep p 17)

- Mamy et al
- Kuinje et al

} mesh contracts indefinitely